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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,211	07/25/2001	Michel Kohl	9997.19US11	5895
23552	7590	10/06/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			VENC, DAVID J	
			ART UNIT	PAPER NUMBER

1641

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,211

Applicant(s)

KOHL ET AL.

Examiner

David J Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to a conjugate, classified in class 436, subclass 543.
- II. Claims 1 and 11-27, drawn to a method, classified in class 435, subclass 7.1.
- III. Claims 28-29, drawn to a kit, classified in class 435, subclass 975.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in a materially different process, such as a process requiring an immunogen.

Inventions I and III are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention I requires a conjugating arm, while Invention III requires a β -lactamase enzyme.

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Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in a materially different process, such as a process for producing and characterizing an immune response.

If Applicants elect Invention I (claims 1-10), then the following species elections are required:

A. Select ONE hapten: (claim 8)

1. nandrolone;
2. testosterone;
3. progesterone;
4. estradiol; OR
5. cocaine.

B. Select ONE β -lactam derivative: (claim 9)

1. carbenicillin;
2. oxacillin;
3. cefuroxime;
4. cefotaxime;
5. methicillin;
6. benzylpenicillin; OR
7. phenoxymethylpenicillin.

C. Select ONE conjugate: (claim 10)

1. nandrolone carbenicillinate;
2. cocaine carbenicillinate;
3. progesterone oxacillinate; OR
4. progesterone benzylpenicillinate.

If Applicants elect Invention II (claims 1 and 11-27), then the following species elections are required:

A. Select ONE detection kit: (claim 17)

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1. BetaSTAR;
2. SNAP Beta Lactam;
3. Penzym;
4. Parallax Beta Lactam assay;
5. Charm Farm Test;
6. Delvo-X-press;
7. Delvotest P; OR
8. Delvotest SP.

B. Select ONE reporter substrate:

1. nitrocefin; (claim 18)
2. cephalexin; (claim 19)

C. Select ONE substance:

1. agents for protecting β -lactamase and penicillin detector; (claim 21)
2. agents for protecting reporter substrate; (claim 21)
3. agents for protecting hapten-inhibitor complex; (claim 21)
4. decontaminating agents; (claim 21)
5. class B β -lactamase; (claim 22)
6. sodium azide; (claim 22) OR
7. phenylbutazone. (claim 22)

If Applicants elect Invention III (claims 28-29), then the following species elections are required:

A. Select ONE β -lactam derivative: (claim 28)

1. carbenicillin;
2. oxacillin;
3. cefuroxime;
4. cefotaxime;
5. methicillin;
6. benzylpenicillin; OR
7. phenoxymethylpenicillin.

B. Select ONE reagent: (claim 29)

1. agents for protecting β -lactamase;
2. agents for protecting reporter substrate;
3. agents for protecting hapten-inhibitor complex; OR
4. decontaminating agents;

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For example, if Applicants elect Invention I(A5)(B1)(C2), then claims 1-10 shall be examined. If Applicants elect Invention II(A1)(B1)(C7), then claims 1, 11-18, 20, 22-27 shall be examined.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Because these inventions are distinct for the reasons given above and the search required for each group is not required for the groups, restriction for examination purposes as indicated is proper.

A telephone call was made to Attorney John Gresens on September 22, 2004, to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

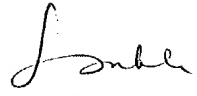
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David J Venci
Examiner
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djv


LONG V. LE
SUPERVISORY PATENT EXAMINER
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12/01/04